User Manual

PARAMETRYS

37-022 V2.1

Date of the first placing on the market of the product: July 2012

CE_{0459}

PARSYS
TELEMEDECINE

10/15/2015 Version

SUMMARY

We thank you for acquiring a multiparametric monitor Parametrys. We hope it will bring you full satisfaction in your everyday medical practice.

1. <u>Components of the Parametrys kit</u>

1.1 Components

Please make sure that your Parametrys monitor includes all of the following:

Standard monitor version:
- 1 multiparametric monitor equipped with: Ref: 25-013
  - 1 reinforced touch screen   Ref: 40-022
  - 1 oximeter cable equipped with a finger sensor [SPO2]   Ref: 23-020
  - 1 blood pressure cable equipped with standard sizes armband [NIBP]:   Ref: 23-063
    - Adult: Ref: 23-056
    - Child: Ref: 23-057
    - Infant: Ref: 23-058
    - Large: Ref: 23-033
- 1 medical power cable (FRIWO: FW7405M/12)   Ref: 16-004
- 1 User Manual Parametrys - EN   Ref: 37-022
- 1 Warranty Certificate - EN   Ref: 37-003

Depending on the selected options:
- 1 ECG cord equipped with banana plugs [ECG]   Ref: 23-039
- 1 dock station   Ref: 25-020
- 1 12-lead Telecardia ECG   Ref: 25-001
- 1 Telecardia Patient cable with 3 secured banana plugs 4 mm   Ref: 23-029
- 1 arm limb clip – RED (AvR)   Ref: 36-007
- 1 arm limb clip – YELLOW (AvL)   Ref: 36-008
- 1 arm limb clip – GREEN (AvF)   Ref: 36-011
- 1 12 to 18-lead Cardialys ECG   Ref: 25-005
- 1 Cardialys Patient cable* (according to options) :
  - 12-lead   Ref: 23-023 A or B
  - 18-lead   Ref: 23-024 A or B
- 1 arm limb clip – BLACK (N)   Ref: 36-020
- 1 "RESET" cable for ECG   Ref: 23-051
- 1 car power cord 12V   Ref: 23-022
- 1 water spray   Ref: 36-006

In the event that one of the above elements was missing, please contact the After-Sales Service mentioned in the section 11.

* Patient cables can have several types of plugs: 4mm banana plugs (Version B) or 4mm clip (Version A); this type should be specified when ordering.

1.2 List and meaning of the symbols used

Symbol	Meaning
⚠	Warning: consult attached documents
📖	Please read the notice
立	BF type applied part
🗑	Do not dispose of in the bin but through the appropriate recycling channels.
((·))	Non-ionizing radiation
🏭	Product manufactured by PARSYS Telemedecine
🌡	Device climatic range of use or storage
S/N	Serial number
CE	Medical device European compliance

1.3 Warnings

PARSYS Telemedicine draws the attention of the user on the following points regarding:

⚠ **Using the device for one patient at a time**

Using Parametrys is exclusively to medical diagnosis of **a single patient at a time**. It cannot be used to establish a medical diagnosis of several patients simultaneously.
It is therefore appropriate to user Parametrys to ensure that the equipment used **is reserved for one patient only**.

⚠ **Presence of other similar medical device in the area of use**

There may be a **danger** if **alarm presets** are used for a similar device to the Parametrys monitor, in a given area, that is to say another medical device that would measure the same parameter as the measured one by Parametrys:
- in the same area of use
- with different alarm limits.

⚠ **Alarm signals disabled: no visual or audible signal will only appear if the measurement alarms limits are exceeded**

Visual and audio alarm signals are **totally disabled** when:
- The measurement mode of the signal is not active,
- The user does not check the "**Enabled**" box in the alarms settings for the measurement (FC, SPO2, NIBP and RESP) (see 4.6.1).

⚠ **Presence of a high frequency surgical equipment in the area of use**

There may be a **risk** (burning) if using a **high-frequency surgical device** together with Parametrys in a given area. It is therefore **imperative not to use** these two devices **simultaneously**.

⚠ **Use of another electro-medical equipment connected to the patient**

There may be a **risk** if using **another electro-medical device** together with Parametrys on the same patient. It is up to the user **to get information** in advance on **possible risks related to the simultaneous use** of such equipment and Parametrys **on the same patient**.

⚠ **Use a defibrillator on the patient connected to Parametrys**

The Parametrys monitor is protected against defibrillation shocks. After a defibrillation shock, a delay of about 5 seconds is however necessary for the resumption of 5-lead ECG monitoring.

⚠ **Using the oximetry sensor (SPO2) on the patient**

It is important that the patient be as quiet and motionless as possible to avoid any unwanted movement that could lead to the appearance of motion artifacts inducing a SpO² value too low or a poor signal quality.

It is also important to take into account of a possible low peripheral circulation of the patient (low perfusion) which could result in the appearance of motion artifacts inducing a SpO² value too low or a poor signal quality.

⚠ **Materials in contact with the skin**

The device is designed and manufactured to **avoid any risk** posed by the materials in contact with the patients or the user. The device is **compliant with the materials biocompatibility directives**. The device's materials don't induce **any toxicity**, **effect** or **residual risks** for children, pregnant and nursing women.

2. Device description

2.1 General introduction

2.1.1 Components

Parametrys includes the following two items:
- A **central unit** including a touch screen, wired sensors and one storage pocket,
- Optional: the **dock** including 2 storage and charging compartments for portable Bluetooth ECG from PARSYS Telemedicine: Telecardia and Cardialys.

1. Monitor with docking station   *2. Monitor without dock*
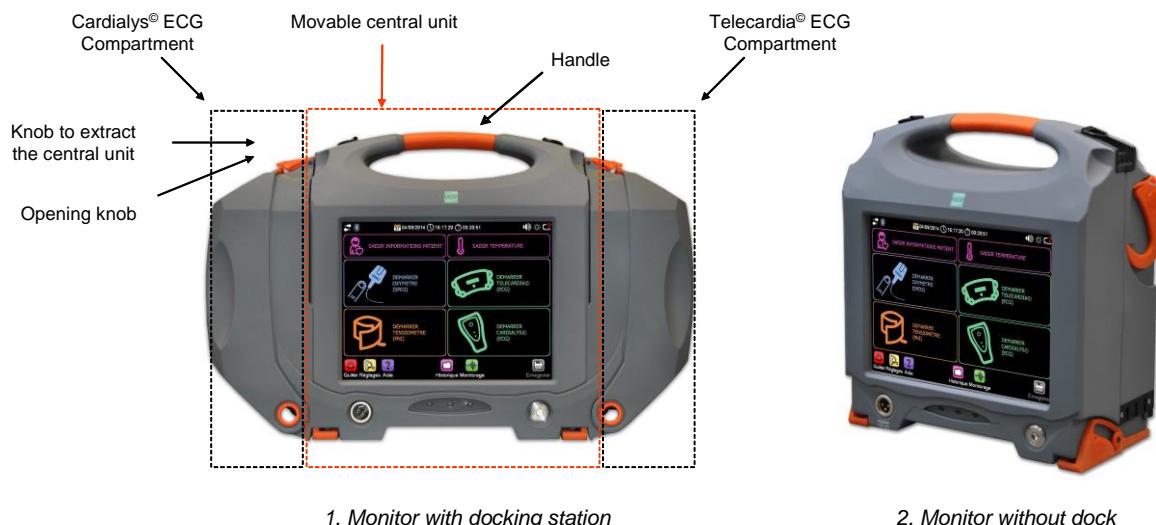
Parametrys is a multiparametric monitor with a touch screen and autonomous battery. It helps to measure:

- **in Exam mode,** the monitor can take the following physiological measures:
  - o the pulse's oximetry (SpO² in %),
  - o the heart rate (number of beats/min),
  - o the non-invasive blood pressure measures (in mm of mercury).

- **in Monitoring mode**, the monitor can observe the following measures:
  - o the pulse's oximetry (SpO² in %),
  - o the heart rate (number of beats/min),
  - o the non-invasive blood pressure measures (in mm of mercury),
  - o the respiratory rate (number of breathings/min) (optional),
  - o a 5-lead ECG tracing (optional).

2.1.2   Integrated wired sensors

Wired sensors are located in the black back pocket with a magnetic clasp:
▪ Blood pressure cable and arm cuff,
▪ Optical sensor of oximetry,
▪ Optional 5-lead ECG cable, with clips plugs.

3. Front side

4. Back side, storage pocket open

⚠ **Sensors and accessories are supplied with the monitor:**
▪ **Do NOT USE other models of sensors and accessories without having previously validated the compliance with PARSYS Telemedicine.**

2.1.3   Non wired Bluetooth sensors (optional)

As an option, your monitor may be equipped with a dock linked to the Telecardia and Cardialys ECGs. The devices are paired with the monitor. They can be stored and recharged in their compartment.

2.1.4   Indicators & buttons

5. Indicators and buttons

Button:
- in front, a single button turns the monitor on and off (ON/OFF button).

Connector:
- in front, a single connector (POWER 12V DC) used to plug the power cord.

Charging indicator of the Monitor:
- **Turned off**: no power cable is connected to the monitor
- **Blinking GREEN light**: charge in progress
- **Non-blinking GREEN light**: monitor is fully charged (100%).

Charging indicator of the Telecardia and Cardialys ECGs:
- **Turned off**: no ECG device in the compartment or ECG device fully charged (100%)
- **Blinking GREEN light**: charging in progress
- **Non-blinking GREEN light**: ECG device is fully charged (100%) (the light switch off then).

> ⚠️ **If the charging indicator of the Monitor is ORANGE or RED, a major malfunctioning is signaled (see Troubleshooting, chapters 10.5 and 10.6).**

2.1.5   Optional: using the ECG compartments of the dock

To open and close the compartments, follow the instructions hereafter:
▪   Press on the bottom of the orange handle located along the compartment
▪   Open by using the slot located on top of the handler.
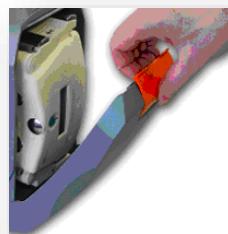
6. Opening of the compartment

To guarantee the **best transport conditions and connections at the charging decks**, the ECG devices and must be placed in their compartments, according to the below images 7 and 8.

7. Right compartment for the Telecardia ECG

8. Left compartment for the Cardialys ECG

2.1.6   Optional: extracting the monitor from its dock

To extract and reinsert the central unit, please follow the instructions hereafter:
▪   Open the orange knobs located on each side of the transportation handle (see image 9)
▪   Pull the knobs up in a vertical position to clear the way for the extraction of the central unit (see image 10).

9. Opening knob

10. Extracting the central unit

2.2 Functionalities

2.2.1 Using the Exam mode

The user chooses his desired exams by pushing on the buttons of the device:
- Pulse's oximetry (SpO² in %)
- Non-invasive pressure (in mm of mercury)
- optional: Telecardia ECG
- optional: Cardialys ECG

2.2.2 Using the Monitoring mode

The user presses on the "**Monitoring**" button to turn on the monitoring screen. It is possible to capture the image of the selected settings on screen and transmit it.
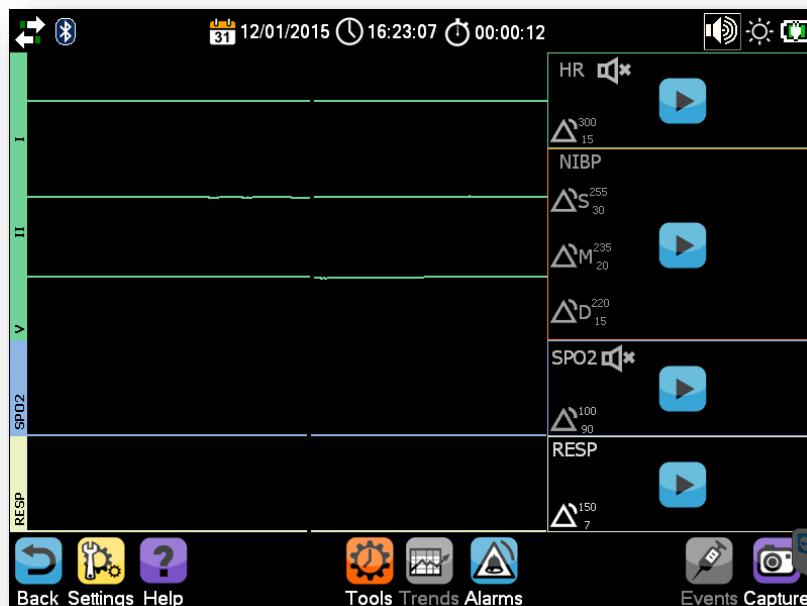
11. Monitoring screen

2.2.3 Data transmission

Parametrys can handle Bluetooth, GPRS and Ethernet network connections.

An active 3G chip can be integrated in the monitor **as an option**.

The Parametrys monitor can communicate via Bluetooth with a Mobile Pilot (TPL Systems) and transmit data compatible with the emergency radio network ANTARES.

2.2.4 Data printing

Parametrys has a compartment made for the USB connectors, located at the back of the monitor. The USB plugs can be used to connect, for instance, a compatible printer.

12. Location of the USB plugs

It is also possible to connect a Bluetooth wireless mobile printer to the monitor.

2.3 Recharging the monitor

Parametrys has its own power with rechargeable batteries:
- Battery type: 2 LIPO (8,4v) elements, with a safety circuit of 6,5 Ah
- Running life and charging indicator: 4h in sleep mode, 2h in full usage
- Charging time: 2h30
- Number of batteries delivered: one, internal and fixed.

Parametrys is delivered without a change of battery: a battery change can only be done by the After Sales Services crew of PARSYS Telemedicine.

2.3.1   Power cable

A low voltage power is necessary to ensure that the battery can be charged and that the Parametrys can be used from a 12V plug (vehicle) or wall plug (100 to 250V).

> ⚠ **Always use the given sector's plug to power the monitor otherwise irreversible damages could occur and would not be covered by the device's warranty.**

Power plug

Charging light

13. Location of the power connector and charging indicator

2.3.2   Battery's level of the monitor

The symbol representing a level of battery is located on the top right side of the monitor's screen when it is turned on: it must be checked **frequently.**

14. Battery levels

> ⚠ **A window appears on the screen when the monitor level battery reaches 12%**

2.4 Turning the device on and off

To turn on the device, press the ON/OFF button until the green light appears. Parametrys will be operational after around 1 minute.

> ⚠ **To turn off the device, press the "Turn off / Exit" button of the software. Using the "ON/OFF" button must stay rare.**

                                              ⟵ ON/OFF Button

15. ON/OFF button

To turn on the device:

Press the ON/OFF button until the green light is on:
- ✓ PARSYS Telemedicine logo appears with the message "***Processing***";
- ✓ software home screen appears after about 1 minute;
- ✓ your monitor is now operational.

> ⚠ **As a standard PC:**
>
> - **press once the ON/OFF button for 1 to 2 seconds is enough to turn on the monitor, even if the display doesn't light up immediately;**
> - **the continued pressure on the button should only be used to force the shutdown of the system in case of freeze.**

To turn off the device:

- ✓ Preferably use the "**Quit**" button ⏻ in the software.
- ✓ Or BRIEFLY press (less than 2 seconds) on the ON/OFF button.

> ⚠ **Using the ON/OFF button in the front of the device to turn off the monitor should be exceptional.**

2.5 Adjusting the angle of the monitor's screen

Parametrys has its own adjusting clip with a vertical orientation, allowing an adjustment of the screen's angle to the surrounding light.

16. Adjusting foot

2.6 Hanging the monitor to a stretcher

Parametrys has 2 straps placed around the transport handle. These straps can be placed outwardly to hang the monitor to a standard stretcher.

17. Straps for stretcher

3. <u>Setup</u>

The Parametrys monitor is delivered with a pre-integrated and operational software.
No software download or setup is necessary.

> ⚠️ **In case of software malfunctioning, we please ask that you:**
> - **NEVER attempt to fix the software by yourself.**
> - **Contact the After-Sales Service of PARSYS Telemedicine.**

4. Use sequences

4.1 Parametrys's main screen
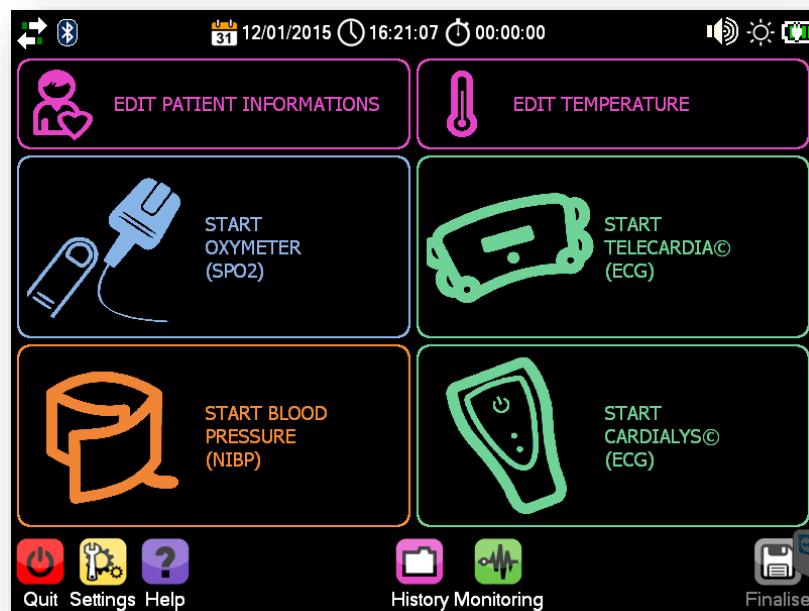
18. Main screen

Indicators:

 : Internal card connection

 : Bluetooth network

 : GPRS network

 : Date

 : Time

 : Monitoring stopwatch (starts at each activation of the monitoring function).

 : Adjusting the volume

 : Adjusting the brightness

 : Battery levels

4.2 Sound and brightness adjusting

Brightness indicator:

- ▪ Press on the icon ☼ in the upper right of the screen to access to the settings window.
- ▪ After setting, press on the "**Accept**" button (or "**Cancel**") to make it disappear.

Sound indicator:

- ▪ Press on the icon 🔊 in the upper right of the screen to access to the settings window.
- ▪ After setting, press on the "**Accept**" button (or "**Cancel**") to make it disappear.
- ▪ Whatever level applied, the sound may not be set below 50%.
- ▪ Each time you start the monitor, the sound is at its maximum in order to reactivate the default alarms settings.

⚠ **Sound setting impacts all the monitor's sound signals, including ALARMS.**

When setting alarms, please always check the level sound setting of the monitor.

4.3 Usage principles

4.3.1 After taking and validating measures
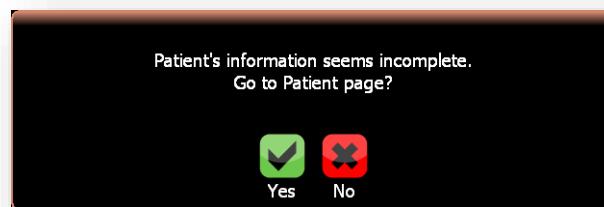
If no patient has been identified before, the following message will appear:
« Patient's information seems incomplete.
Go to Patient page? »

You can then go back to the identification function in order to link a patient's name with data.

#### 4.3.2 To keep, cancel or retake measures:
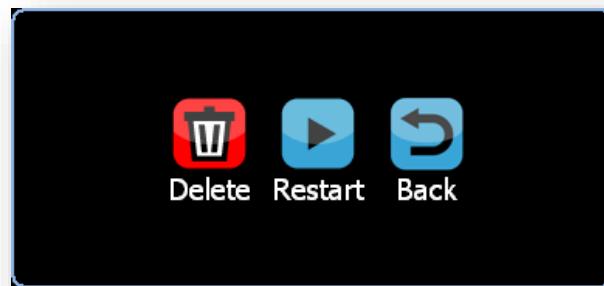
Press again the sensor's button:
- « **Delete** »:   The measure on screen **is not** recorded.
- « **Restart** »:   Retake a measure, the previous measure **will no longer be** available.
- « **Back** »:   Return to the main screen, the measure **is** recorded.

⚠️ **In exam mode (no monitoring), we recommend that you perform the measures and then use the "Finalize" button.**

If you use the "Finalize" button after each measure, you must enter each time the Patient ID.

Keeping the measure on screen is not enough to record it: you must then press "Finalize".

4.3.3   Record or delete data

In the bottom menu, the « **Finalize** » button allows the following:
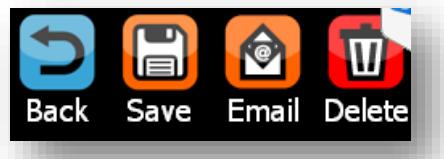
- ▪ « **Back** »:   Return to the main screen, the measures are retained but not recorded.
- ▪ « **Save** »:   Save the measures taken in the final exam file.
- ▪ « **Email** »:   Email the measures taken via a GPRS or Ethernet connection.
- ▪ « **Delete** »:   Clear all the measures taken (confirmation needed).

⚠ **Keeping the measures on the screen is not enough to save them permanently: you have to use the "Finalize" button.**

4.4 Exams protocols

4.4.1 Capturing patient data
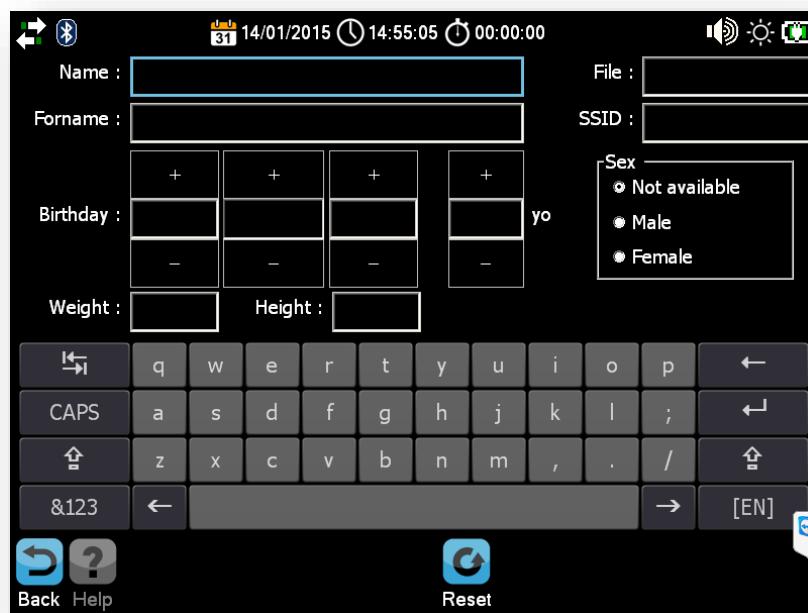
19. Edit Patient Information screen

1) Press the button « **EDIT PATIENT INFORMATIONS** » on the main screen.
2) Place the cursor on the desired field.
3) Capture data using the touch keyboard.
4) Two actions are available:
   - « **Back** »:   Validate the captured Patient's information and go back to the main screen.
   - « **Reset** »:   Erase the captured Patient's information.

⚠ **If you take measures without first capturing patient data, a reminder appears during data recording.**

4.4.2   Setting devices

1. Press on the "**Settings**" button on the main screen.
2. Choose the chosen device to access its control panel.
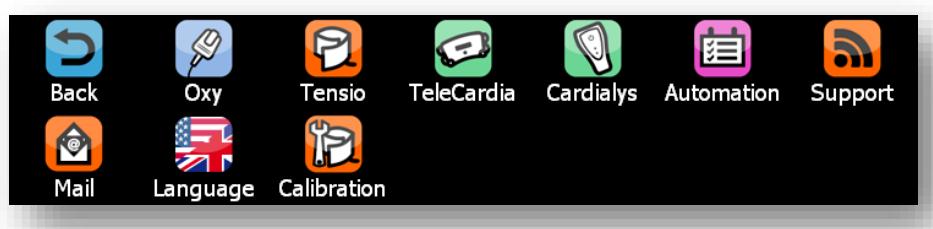
- ▪ **« Back »**:   Return to the main screen.
- ▪ **« Oxi »**:   Set the oximetry measurement SPO2.
- ▪ **« Pressure »**:   Set the blood pressure measurement NIBP.
- ▪ **« Automation »**:   Set data printing, converting and recording.
- ▪ **« Support »**:   Allow remote control of the device by an operator.
- ▪ **« E-mail »**:   Set the e-mail system.
- ▪ **« Language »**:   Choose the device use language.
- ▪ **« Calibration »**:   Calibrate the device blood pressure.

Optional:
- ▪ **« Telecardia »**:   Set Télécardia ECG.
- ▪ **« Cardialys »**:   Set Cardialys ECG.

4.4.3   Using the thermometer in Exam mode

1) Press the button **« Edit Temperature »** on the main screen.
2) Take the patient's temperature.

3) Enter the temperature on the screen with the buttons "**+**" and "**-**", then press the **« Accept »** button to validate the data.

4.4.4 Using in the blood pressure device in Exam mode
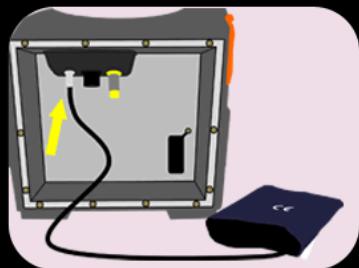
C. Press the "**START BLOOD PRESSURE (NIBP)**" button on the main screen to start the capture.

D. In any case, the NIBP control panel appears. Check the settings then press the "**Accept**" button ✅ to start the capture.

E. At any time during the capture, you can stop the device by pressing the « **Cancel** » button ❌.

F. When the capture is complete, the final measures appear on the main screen.

4.4.5 Using the oximeter in Exam mode

C. Press the « **START OXIMETER (SPO2)** » button on the main screen to start the capture.

D. At any time during the capture, you can stop the device by pressing the « **Cancel** » button .

E. When the capture is complete, the final measures appear on the main screen.

4.4.6   Optional: using the Telecardia ECG in Exam mode

If you have a Telecardia ECG, we please ask that you follow the procedures hereafter in order to obtain a simultaneous 12-lead 12-channel ECG trace from the patient:
1) Press the « **START TELECARDIA (ECG)** » button on the main screen, the message « **READY TO CAPTURE.** » appears.
2) You can then start the ECG exam, the trace will be transmitted automatically to the monitor.

Capture ECG

D Press briefly on the GREEN button to open the ECG arms.

⚠️ NEVER use FORCE to open the arms.

Capture ECG
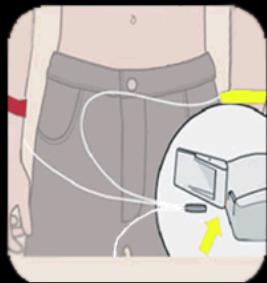
E Connect the ECG limb clips cable in the socket on the LEFT side of the unit.

⚠️ Gently turn the cable's RED mark pointing UP.

Capture ECG
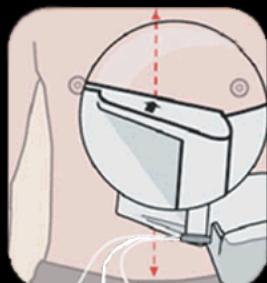
J Keep the electrodes in contact with the skin.

Both you and the subject should stay as **STILL** and **CALM** as possible for the 15 seconds of capture.

An audible signal (a beep or a voice) sounds at the end of capture and automatic data transmission.

4.4.7 Optional: using the Cardialys ECG in Exam mode

If you have the ECG Cardialys option, we please ask that you follow the procedures hereafter in order to obtain a simultaneous 12 to 18-lead ECG trace from the patient:

1) Press the « **START CARDIALYS (ECG)** » button on the main screen, the message « **READY TO CAPTURE.** » appears.
2) You can then start the ECG exam, the trace will be transmitted automatically to the monitor.
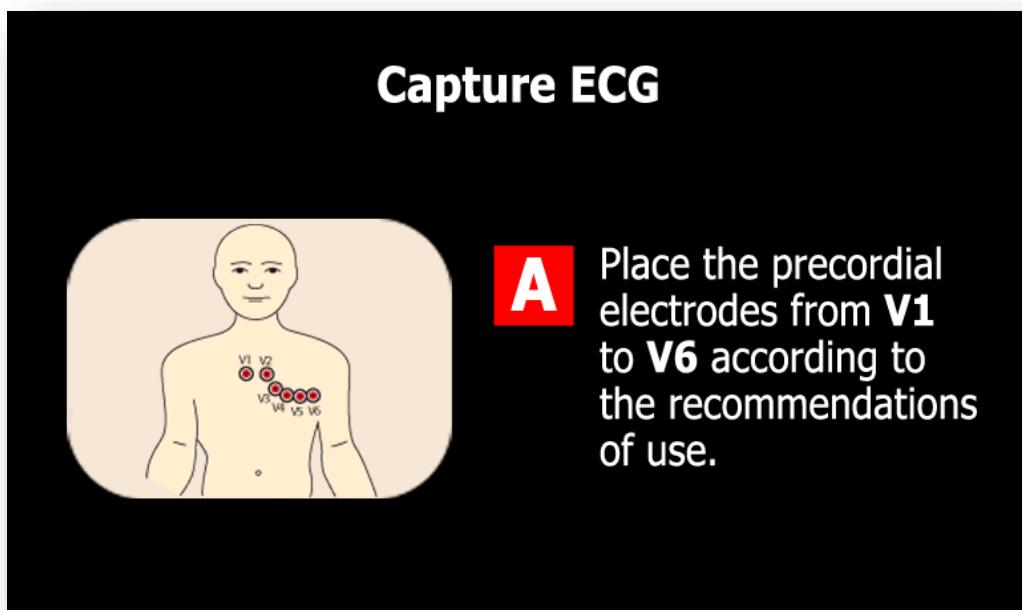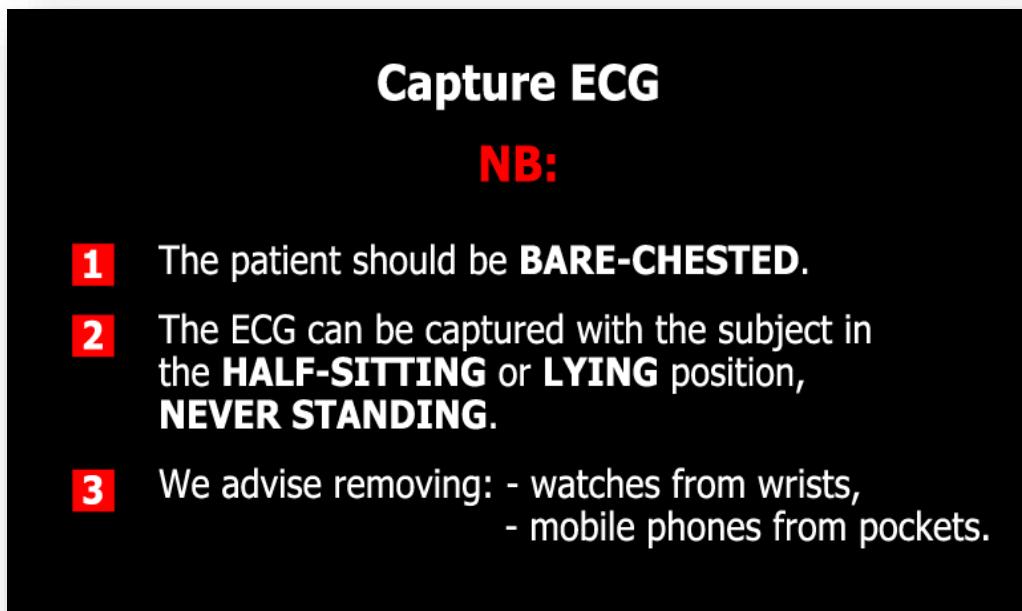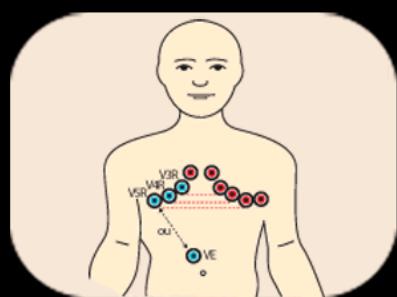
Capture ECG

B Position the **V3R**, **V4R** and **V5R** electrodes (symmetrically from V3, V4 and V5).

⚠️ **V5R** can also be positioned in **VE** according to practice.

Capture ECG
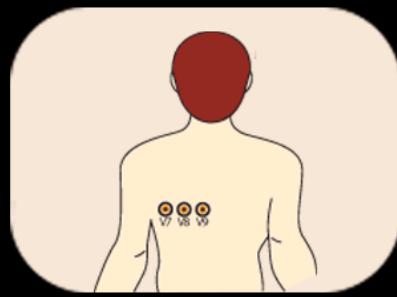
C Position the V7, V8 and V9 electrodes on the subject's back.

Capture ECG
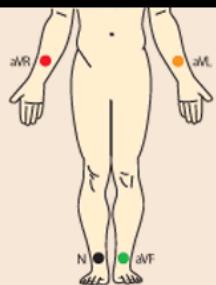
D Position the peripheral electrodes: **aVR**, **aVL**, **aVF** and the **neutral**.

Capture ECG
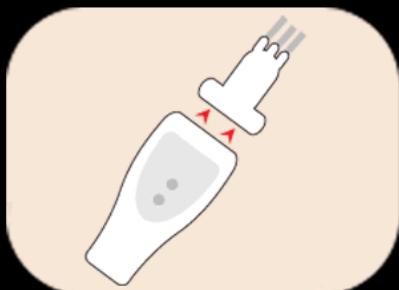
E Check the good connection between the differentiator and the wire electrodes cable.

(Normally held together by a clamp)

![PARSYS TELEMEDECINE]	User Manual Parametrys	Ver 2.1

Capture ECG

H The BLUE light is displayed on the differentiator unit to indicate that the RADIO LINK is ESTABLISHED.

Capture ECG
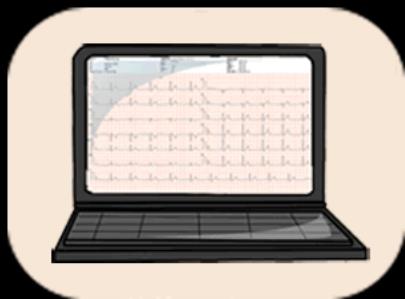
I The ECG trace is automatically sent to the terminal (Personal Computer or Touchscreen Tablet).

4.4.8 Display of the ECG traces obtained with Telecardia or Cardialys

It is possible to examine a trace in greater details by using the following functions:

■ **Examination of the trace**
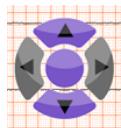
The cursor allows moving around the tracing on screen:
- The arrows can move the trace,
- The round central button can move the cursor itself.

The « **+** » and « **-** » buttons help enlarge or shrink the trace's image.

■ **Settings**

The « **Settings** » button is used to choose display formats and trace's measures:

: **Strips**

: **V Report**

: **H Report**

: **Grid**

: **Measures**

: **Calipers**

✓ « **Strips** »: leads are displays in strips mode, classified vertically.

✓ « **V Report** »: vertical printing format, « portrait » mode.

✓ « **H Report** »: horizontal printing format, « landscape » mode.

✓ « **Grid** »: display or non-display of the background's grid.

✓ « **Measures** »: display or non-display of ECG measures:

✓ « **Calipers** »: display or non-display of Calipers (measurement tool).

4.5 Monitoring

4.5.1 Launching the Monitoring's function

Press the « **Monitoring** » button [icon] on the main screen:
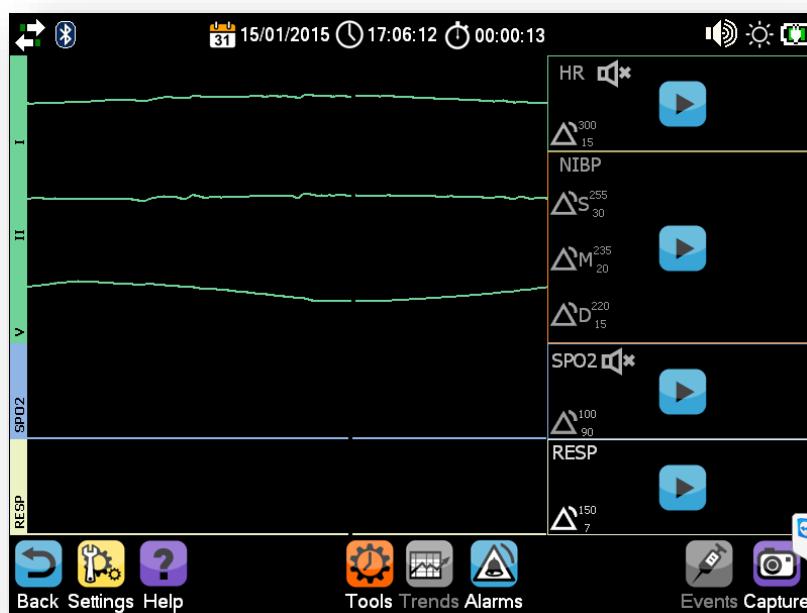
20. Monitoring screen

[icon] : Start taking measures.

[icon] : Activate or turn off the sound signal during measures.

[icon] : Activate and adjust the **audible** and **visual** alarm signals.

[icon] : View and validate the alarm messages.

4.5.2   Setting the devices

1. Press on the « **Settings** » button on the monitoring screen bottom.
2. Press the chosen device to access the control panel.
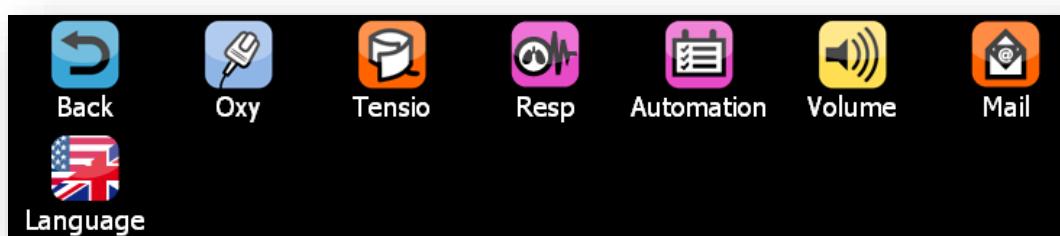
- « **Back** »:   Return to the monitoring screen.
- « **Oxi** »:   Set the oximetry measurement SPO2.
- « **Pressure** »:   Set the blood pressure measurement NIBP.
- « **Resp** »:   Set the respiration measurement RESP.
- « **Automation** »:   Set data printing, converting and recording.
- « **Volume** »:   Adjust the volume of the device.
- « **E-mail** »:   Set the e-mail system.
- « **Language** »:   Choose the device use language.

4.5.3   Handling support tools: Stopwatch, Timer, Metronome

1. Press the « **Tools** » button on the monitoring screen.
2. Choose:
    - « **Stopwatch** »:   Start the Stopwatch support tool.

    - « **Metronome** »:   Start the Metronome support tool.

    - « **Timer** »:   Start the Timer support tool.
3. Start the selected tool by pressing the corresponding button.

4.5.5   Using the blood pressure device in Monitoring mode

C. Start the Monitoring mode by pressing the "**Monitoring**" button [icon] on the main screen.

D. To start the blood pressure (NIBP) monitoring, press on the button [icon] localized on the NIBP area on the right of the Monitoring screen. Then press on the "**Start**" button [icon] to start the NIBP monitoring.

E. The NIBP control panel appears. Check the settings, then press the "**Accept**" button [icon] to start the monitoring.
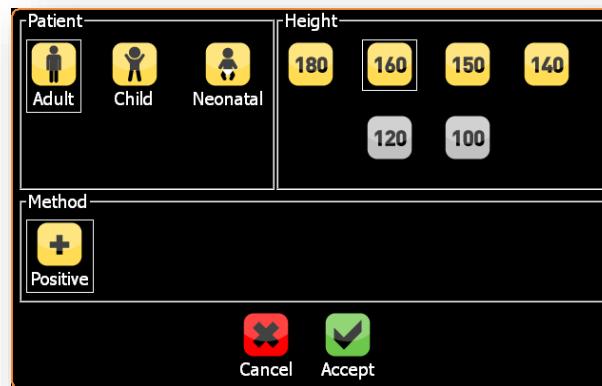
F. The NIBP measure is automatically displayed on the NIBP area.

4.5.6 Using the oximeter in Monitoring mode

Capture pulse oximetry

A Remove the sensor from the back pocket and check cable connection.

Capture pulse oximetry

B Put the subject's index finger inside the sensor.

C. Start the Monitoring mode by pressing the "**Monitoring**" button on the main screen.

D. To start the oximetry (SPO2) monitoring, press on the button localized on the SPO2 area on the right of the Monitoring screen. Then press on the "**Start**" button to start the SPO2 monitoring.

E. The SPO2 measure is automatically displayed on the SPO2 area.

4.5.7 Precisions on using the optional ECG's cable with 5-lead clips

ECG, Breathing and Heart Rates:
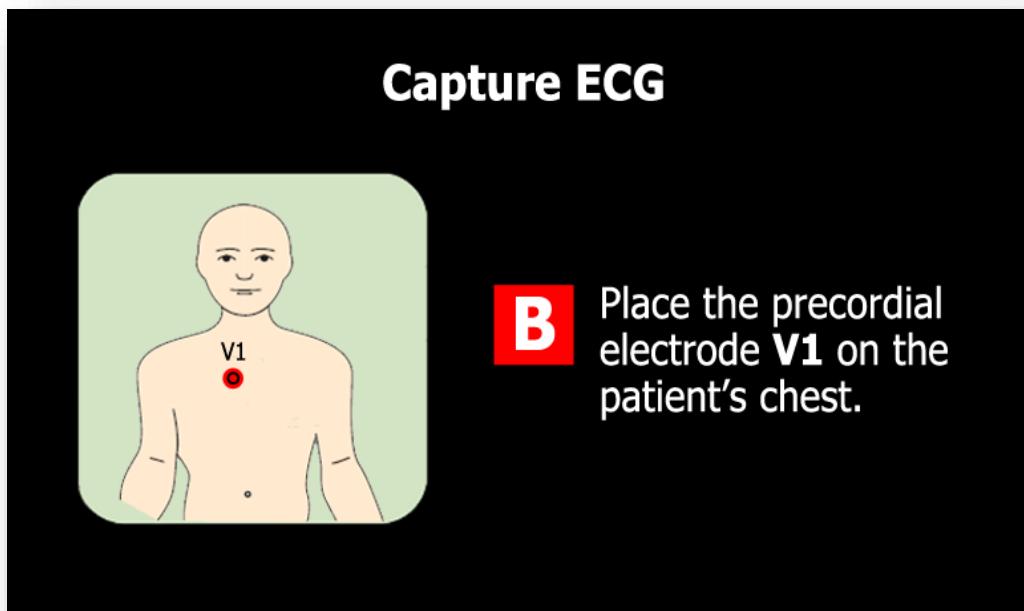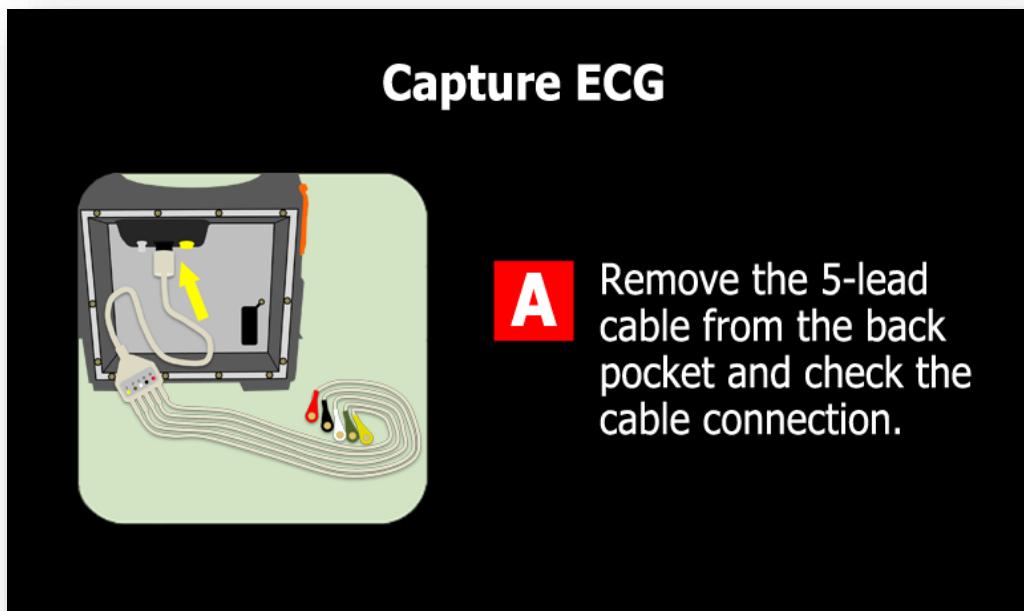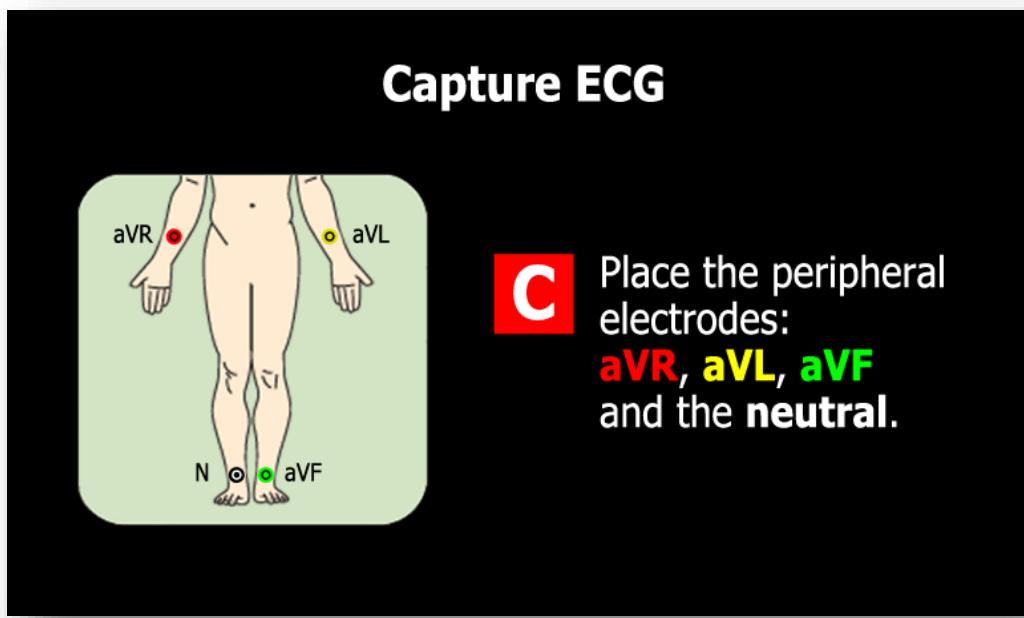
E. Start the ECG Monitoring by pressing the "**Monitoring**" button on the main screen.

F. To start the heart rate (HR) monitoring, press on the button localized on the HR area on the right of the Monitoring screen. Then press on the "**Start**" button to start the HR monitoring. The HR measure is automatically displayed on the HR area.

G. To start the breathing rate (RESP) monitoring, press on the button localized on the RESP area on the right of the Monitoring screen. Then press on the "**Start**" button to start the RESP monitoring. The RESP measure is automatically displayed on the RESP area.

4.5.8 Recording and sending the monitoring data

1. At all times, you can record or send data by pressing the "**Capture**" button on the monitoring screen.
2. Choose one of the following actions:
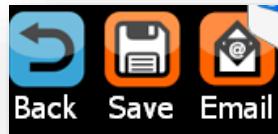
- ▪ « **Back** »:   Return to the monitoring screen.
- ▪ « **Save** »:   Save the capture in the final exam file.
- ▪ « **Email** »:   Email the capture via a GPRS or Ethernet connection.

4.6 Alarms management

4.6.1 Access to alarm settings: conditions and limits

▪ **High priority alarm conditions**

PARSYS Telemedicine has classified all alarm conditions of Parametrys monitor in **high priority**, and declined audible and visual alarm signals in accordance with this priority.

> ⚠ **The definition of priority levels can't be set or modified by the user of the monitor or the Client Administrator.**

▪ **Limited access to the settings of the alarms system**

The user **has the ability**:
✓ enable, disable, reset audible and visual alarm signals related to a measure (HR, NIBP, SPO2, RESP),
✓ set the minimum and maximum alarm limits associated to the measure,
✓ adjust the general audio level of the device, which affects audible signals of all alarms,
✓ enable, disable and set the pause of a particular alarm.

The user **can not**:
✓ enable or disable the visual alarm signal related to a measure without enable or disable the associated audible alarm signal (the reverse is temporarily possible via the audio pause function),
✓ enable alarm signals related to a measure if this type of measure is this measure is inactive,
✓ change the minimum audio level of the monitor (set at 50%), which affects audible signals of all alarms,
✓ change the maximum audio pause time of an alarm (set to 90 seconds).

4.6.2 Monitoring alarms settings

▪ **Reading of alarm icons related to measures (HR, NIBP (S, M, D), SPO2 and RESP):**
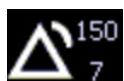
: Alarm signal **activated**, with minimum and maximum values limits

: Alarm signal **disabled** (display without measurement)

: Alarm signal **disabled** (display during measurement)

- **Enabling / Disabling an alarm signal:**

✓ Press on the alarm icon corresponding to the measure (HR, SPO2, NIBP, RESP) to access to the alarm settings window.

   o Check the « **enabled** » check box to activate the corresponding measurement alarm.

   o Or uncheck the « **enabled** » check box to disable the corresponding measurement alarm.

⚠️ **If the « Enabled » is unchecked, the alarm corresponding to the measure (HR, SPO2, NIBP, RESP) is inactive: no visual or audible signal will appear in case of measurement alarm over limits.**

✓ When an alarm is disabled:

   o the icon appears when measuring.

   o the icon appears when no measuring.

- **Resetting a disabled alarm:**

When an alarm is disabled, the user can program the **alarm activation automatic recovery** after a defined time.

✓ Press the alarm icon corresponding to the measure (HR, SPO2, NIBP, RESP) to access to the settings window.

✓ To activate the reset function:
   1. check « **Automatic reset in** »,
   2. set the restart time using the input window,
   3. then validate.

- **Alarm limits settings:**

✓ Press the alarm icon corresponding to the measure (HR, SPO2, NIBP, RESP) to access to the settings window.

✓ Use the touchscreen keypad to possibly change the default limits values.
   1. « **Finish** »: save the entered value.
   2. « **Default** »: restore the default limits values.

Default alarm limits values:

Caption	Name	Min	Max
CF	Heart rate	15	300
NIBP S	Systolic pressure	30	255
NIBP A	Average pressure	20	235
NIBP D	Diastolic pressure	15	220
SPO2	Saturation	0	254
RESP	Breathing rate	7	150

- **Alarms sound level settings:**

Sound indicator:
- Press on the icon ▐█ in the upper right of the screen to access to the settings window.
- After setting, press on the "**Accept**" button (or "**Cancel**") to make it disappear.
- Whatever level applied, the sound may not be set **below 50%**.
- Each time you start the monitor, the sound is at its maximum in order to reactivate the default alarms settings.

> ⚠ **Sound setting impacts all the monitor's sound signals, including ALARMS.**
>
> **When setting alarms, please ALWAYS check the level sound setting of the monitor (see 4.2).**

- **Disabled alarms in case of inactive measurement mod:**

> ⚠ **If the measurement mod is inactive, visual and audible alarms are disabled by default.**

- **Presence of other similar medical device in the area of use:**

> ⚠ **There may be a danger if alarm presets are used for a similar device to the Parametrys monitor, in a given area, that is to say another medical device that would measure the same parameter as the measured one by Parametrys:**
>   o **in the same area of use,**
>   o **with different alarm limits.**

4.6.3 Alarms audio mute function

It's possible to temporarily stop the alarms audio function (not visual):

▪ Press the alarm icon [icon] in the menu in the screen bottom,

▪ Press the Audio mute icon [icon] ,

▪ On the screen's top right, this icon [icon] appears to specify the Audio mute status.

⚠ **The default audio mute time was set at 30 seconds.**
This mute time may not exceed 90 seconds.
The audio mute time is determined and set by the manufacturer: in any case, it cannot be set by the user or the Client administrator.

▪ **Alarms audio unmute function**

It's possible to restore the audio alarms function (not visual) before the automatic recovery (set by default at 30 seconds):

▪ Press the alarm icon [icon] in the menu in the screen bottom.

▪ Press the Audio unmute icon [icon] .

▪ **Maximum audio mute time**

The maximum audio mute time allowed by the device is 99 min 59 s.
The maximum audio mute time chosen and set by the manufacturer is **90 seconds**: in any case, it cannot be set by the user or the Client administrator.

4.6.4   Alarms and alarm messages

When an alarm occurs, the signal is both:
- **Audible**: alarm tone (except in **Audio Mute** status, see 4.6.3)
- **Visual**: **FLASHING RED** light on the screen bottom:
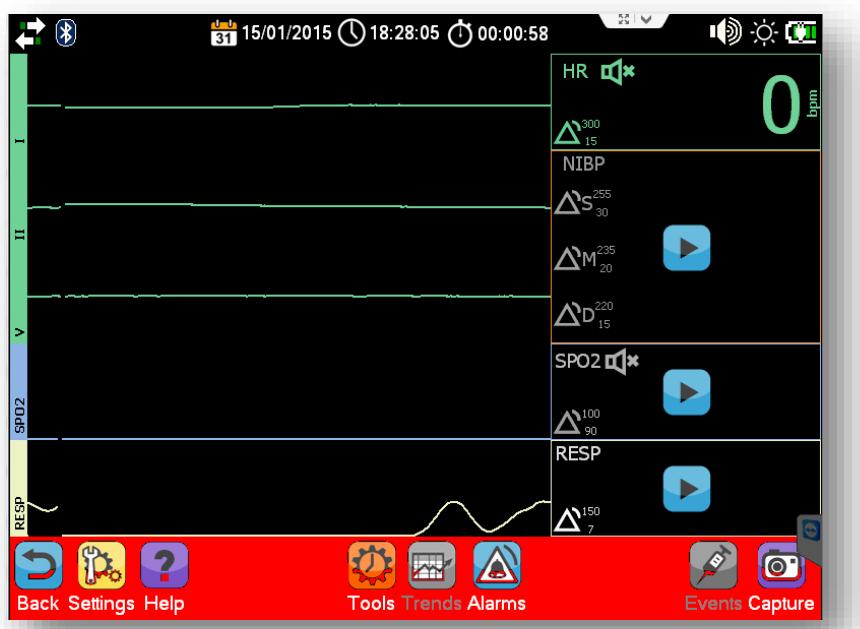
21. Alarm mode on monitoring screen

To stop the alarm:

- It is necessary to read the alarm message by pressing the "**Alarms**" button then pressing on the "**Validation**" button to stop the alarm:
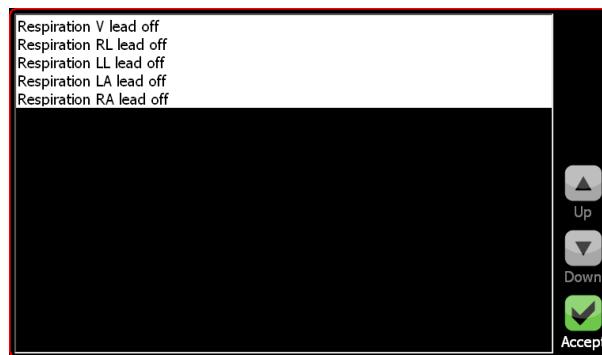
- Read the message and press on the « **Accept** » button .

4.7 Managing the collected data

4.7.1 Analyzing recorded data

22. Recorded exams history

1. Press on the "**History**" button on the main screen.

2. Use the "**Up**" and "**Down**" arrows to browse the list.
3. Press twice on the selected line to access recorded data.

4.7.2 Recorded data management

1. Press on the "**Options**" button on the History screen.
2. Press on the desired data management action:
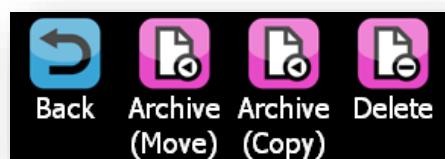
- ▪ "**Back**":   Return to the History screen.
- ▪ "**Archive (Move)**":   Move the exam into the file "**Archives**".
- ▪ "**Archive (Copy)**":   Copy the exam into the file "**Archives**".
- ▪ "**Delete**":   Permanently delete the exam from the History (confirmation needed).

4.7.3 Recorded data sharing

22. Recorded exam display

The access to the "**Share**" function is also possible after a capture from the monitoring screen.

4.7.3.1 Data printing

1. Press on the « **Share** » button on the History screen.
2. Press on the desired printing action:
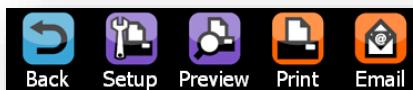
- « **Back** »: Return to the selected recorded data.
- « **Setup** »: Adjust the printing settings and select the printer.
- « **Preview** »: Open a print preview of the selected recorded data.
- « **Print** »: Start printing the selected recorded data.

4.7.3.2 Data transmission

1. Press on the « **Share** » button on the History screen.
2. Press on the desired sending action:
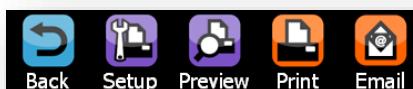
- « **Back** »: Return to the selected recorded data.
- « **Email** »: Send by Email the selected recorded data.
- « **Antares**»: (*Optional*) Send via the Antares emergency network the selected recorded data. The function launches the Bluetooth searching of the Antares connected device.

4.8 Help

4.8.1   Help with using medical devices

1. Press on the « **Help** » button .
2. Select the chosen device to access functioning illustrations.

- ▪   « **Back** »:   Return to the main screen or the previous screen.
- ▪   « **Oxi** »:   Display the oximetry SPO2 help (see 4.4.5).
- ▪   « **Pressure** »:   Display the blood pressure NIBP help (see 4.4.4).

Optional:
- ▪   « **Telecardia** »:   Display the Telecardia ECG help (see 4.4.6).
- ▪   « **Cardialys** »:   Display the Cardialys ECG help (see 4.4.7).
- ▪   « **ECG** »:   Display the ECG Monitoring help (see 4.5.4).

4.8.2   Nurse protocols (optional)

Press on the "**Protocols**" button to access the menu, then select the desired nurse protocol to display it on the screen. Arrows allow you to go from one step to another.

> ⚠ **The installation of the optional "Nursing Protocols" completely replaces the "Help" function (see 4.8.1).**

4.8.3   Remote control

1. Contact the After-Sales Services of PARSYS Telemedicine (see 11.).

2. Press on the "**Settings**" button then press on the "**Support**" button to activate the device remote control by an operator.

5. <u>Software update</u>

The Parametrys monitor is delivered with a preinstalled and operational software. The possible updates are done during maintenance. For each intervention, PARSYS Telemedicine contacts you to explain the updating procedures to follow.

> ⚠ **We please ask you to:**
> - **NEVER ATTEMPT to update the software by yourself,**
> - **Contact the After-Sales Services of PARSYS Telemedicine for any other questions.**

6. Technical features of the monitor

6.1 Main features

Parametrys is a monitor made for an emergency use outside:

- class: IIb
- dimensions: 310 x 277 x 150 mm (without dock),
                                                            360 x 300 x 150 mm (with dock)
- weight: around 4 Kg (without dock)
                                                            6 Kg (with dock)
- materials / waterproofness norm: IP54
- operating temperature: 5 ~ 45° C
- recharging temperature: 5 ~ 40°C
- fret and storage temperature: -10 ~ 50°C
- operating atmospheric pressure: from 700 mb to 1060 mb
- recharging atmospheric pressure: from 700 mb to 1060 mb
- fret and storage atmospheric pressure: from 500 mb to 1060 mb
- operating relative humidity: from 30% to 75%
- recharging relative humidity: from 30% to 75%
- fret and storage relative humidity: from 10% to 85%
- electromagnetic conformity: EN 60 601-1-2
                                                            60601-1
                                                            60601-2-59
                                                            60601-1-8

6.2 ECG monitoring

- Monitoring functions done by an integrated 3/5-lead ECG card with alarms.
- Monitoring selected 3 and 5-lead ECG with I, II, III, AvR, AvF, V1 to V6. (1 free electrode assignable to one of the rapid lead).
- Commutable leads (by ''touch screen'').
- Selection of the horizontal or vertical gain: gain 5, 10 and 20 mm/mV
- Detection of the pacemaker's spike: from 4 to 700 mV of a length comprised
                                                            between 0.2 and 2ms.
- Range for Heart Rate's measurements: Adult: 15-300 bpm
                                                            New Born / Pediatrics: 15-300 bpm
- Precision: 1% of 0 to 100 bpm, 2% above
- Resolution: 1 bpm
- Protection:
    o Against defibrillation's shocks (> 5kV),
    o Against external electromagnetic interferences (H.F.)
- Answers in rates:
    o Diagnostic modes: 0.05 to 120 Hz - Monitoring: 0.5 to 75 Hz - Operation: 1 to 25 Hz.
- Grading signal: 1mv +/- 5%
- Rejection in common mode (50-60Hz):   > 80 dB
- Measuring range: - 20 mV ~ 2.0mV (+/- 5mV)
- Alarm settings: +/- 0.8 mV
- High and low alarms: 15 to 300 bpm

6.3 Breathing rate

Measure of the breathing rate done with one of the ECG wires (D1 or D2):

- Measuring method :   by impedance variations (DII)
- Measuring range Adult, Pediatrics and New Born: from 1 to 150 bpm
- Resolution: 1 bpm
- Precision: ± 2 bpm
- High and Low Alarms (Adult and Pediatrics):   from 1 to 150 bpm
- Apnea detection

6.4 Oximetry (SPO2)

- Measuring range: 0 ~ 100%
- Resolution: ± 1%
- Precision: +/- 2 from 100 to 80%, +/-3 from 79 to 70%
- Measuring range of pulse rate: 0 to 254 bpm
- Resolution: 1 bpm
- Precision: +/- 2bpm or 2%
- High and low Alarms: 0 ~ 254 bpm

6.5 Blood pressure (NIBP) (Non-invasive blood pressure)

- Measuring method: oscillometric
- Measuring mode:
    o Manual – Automatic (from 1 to 240mn of interval between each measure).
    o Automatic (customizable cycles).
- Unit of measure: mmHg
- Measuring range: Adult Systolic / Diastolic, 15 to 255mmHg
- Measuring resolution: 1 mm Hg
- Measuring precision: +/- 5mmHg on average
                                                       +/- 8mmHg maximum
- Alarms: high and low on Systolic – Medium – Diastolic
    o Systolic: from 30 to 255 mmHg in adult mode, 30 to 135 mmHg in new born mode
    o Medium: from 20 to 235 mmHg in adult mode, 20 to 125 mmHg in new born mode
    o Diastolic: de 15 to 220 mmHg in adult mode, 15 to 110 mmHg in new born mode

6.6 Central (main) unit

- Processor: Atom Z530 (Intel)
- Battery recharge card compatible with car power (10V → 15V DC).
- Power: Input: 110-240V ~/ 50-60 Hz /1.1A
                              Output: 12v, max. current consumption 3,8A DC
- Power supply model: FRIWO Desktop Power Supply
                                                       Model: FW7405M/12
- battery: internal Lithium Polymer 7,4V/6500mAh
- battery life: 3 years life cycle
- Bluetooth connectivity version 2.0 (EDR) Class 1 (100 mW).
- Optional: WiFi and GPRS connectivity
- Static Hard disk: 8 Gb
- Touch screen: 10' resistive (usage with a glove is possible).
                                                       Reinforced glass slab (6mm), complies with
                                                       UL1950 resistance standard (equivalent to a
                                                       500gr ball's fall from 1.3m in the center of the
                                                       slab).
- Screen: 10.4' SVGA (800x600).

6.7 Protecting cover

The protecting cover has the following functions:

- Storage and recharge of the equipment and accessories.
- Protection index of IP54 on the entire station, except for the case made for accessories (cables, clips ...).
- Cushioning of the station in operation: Straps for stretcher,
  Transport handle,
  Adjusting clip.
- Protected (IP54) external connectivity (RJ45, RJ11) and access to protected low pressure energy (IP54).
- Transparent to radio waves for the correct functioning of the Bluetooth™ network (no metallic cover).
- Materials: PA6 + Rubber Spray finish
- Reinforced touch screen.
- Connectivity: 1 x RJ45 (Ethernet network) + 1 x USB A Host V1.1/2.0 (peripheral USB printer type) + 1 x USB B Client V1.1/2.0 (emergency USB).

7. Electromagnetic emissions

Table 1: Directives and MANUFACTURER'S statement – ELECTROMAGNETIC EMISSIONS

For all DEVICES and EM SYSTEMS

Directives and manufacturer's statement – electromagnetic emissions		
The device is made to be used in the electromagnetic environment specified below. The client or user of the device must ensure that the device is used in such environment.		
Emission trials	**Conformity**	**Electromagnetic environment – directives**
RF Emissions CISPR 11	Group 1	The device uses RF energy only through his internal functions. As a consequence, its RF emissions are very weak and are not likely to cause interferences in a nearby electronic device.
RF Emissions CISPR 11	Class B	The charging power box (catalogue product) must solely be used with the device in sleep mode, disconnected from the patient.
Harmonic Emissions CEI 61000-3-2	Non applicable	
Pulse fluctuations/ Flicker CEI 61000-3-3	Non applicable	

Table 2 – Directives and MANUFACTURER'S statement – electromagnetic IMMUNITY

For all DEVICES and EM SYSTEMS

Directives and manufacturer's statement – electromagnetic immunity			
The device is made to be used in the electromagnetic environment specified below. The client or user of the device must ensure that the device is used in such environment.			
Immunity trials	**Trial level CEI 60601**	**Conformity level**	**Electromagnetic environment – directives**
Electrostatic shocks (ES) CEI 61000-4-2	+/- 6 kV in contact +/- 8 kV in the air	Conforms	Floors must be made of wood, concrete or ceramics. If the floors are topped with synthetic materials, it is important that the relative humidity remains at 30% at least.
Magnetic field at the rate of the electric network (50/60 Hz) CEI 61000-4-8	3 A/m	Conforms	Magnetic fields at the rate of the electric network must have the distinctive levels of a representative place located in a commercial or hospital environment.

Table 3 – Directives and MANUFACTURER'S statement – electromagnetic IMMUNITY

For all DEVICES and EM SYSTEMS

Directives and manufacturer's statement – electromagnetic emissions			
The device is made to be used in the electromagnetic environment specified below. The client or user of the device must ensure that the device is used in such environment.			
Emission trials	**Trial level CEI 60601**	**Conformity level**	**Electromagnetic environment – directives**
RF conducted disturbances CEI 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff	The portable and mobile RF communicating devices should be not used nearer of any part of the medical devices, including cables, than the recommended separation distance, calculated from the transmitter frequency applicable equation. **Recommended separation distance** **d= 1,2√P** **d= 1,2√P** from 80MHz to 800MHz **d= 2,3√P** from 800MHz to 2,5GHz
RF radiated disturbances CEI 61000-4-3	3 V/m from 80 to 2,5GHz	3 V/m	where **P** is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m) of separation. It should that field strengths from fixed RF transmitters, as determined by an electromagnetic survey on site [a], should be less than the compliance level in each frequency range [b]. Interferences may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: to 80MHz and to 800MHz, the higher d range frequency applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM / FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it should be considered to proceed to an electromagnetic survey on site. If the measured field strength in the location where the medical device is used, exceeds the applicable RF compliance level above, it is necessary to observe the behavior of the medical device, to check that the operation is normal. If abnormal performances are observed, additional measures may be necessary, such as reorienting or repositioning of the medical device on its operation site. [b] In the frequency range of 150kHz to 80MHz, it is appropriate that the field strengths are smaller than 3 V/m.			

Recommended separation distances between portable and mobile RF communicating devices and the medical device.

The medical device is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communicating device (transmitter), and the medical device, as recommended below, according to the maximum power emission of the communication device.

Transmitter maximum assigned power output (W)	Separation distance according to the transmitter frequency (m)		
	from 150kHz to 80MHz $d= 1,2\sqrt{P}$	from 150kHz to 80MHz $d= 1,2\sqrt{P}$	from 150kHz to 80MHz $d= 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum assigned transmission power is not given above, the recommended separation distance **d** in meters (m) can be estimated by using the transmitter frequency applicable equation, where **P** is the characteristic of the transmitter maximum transmission power in watts (W) according to its manufacturer.

NOTE 1: to 80MHz and to 800MHz, the higher d range frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8. Maintenance

8.1 Cleaning / Disinfection

Cleaning and disinfection of the device can be done using cotton or a wipe soaked with a product like STERANIOS or an equivalent (glutaraldehyde solution 2%) on the plastic box. If some items have been in contact with blood, the recommended disinfecting product is INCIDIN FOAM.

8.2 Procedure to follow after a device's fall

Do NOT use the device if there are any mechanical damages to it after the fall. The device must be returned immediately to the After-Sales Services of PARSYS Telemedicine.

8.3 Procedure to follow in case it rains or snows

When it rains or snows, splashing water drops or snowflakes on the touch screen can disrupt the use of the software (trigger non-desired functionality). It's necessary to check that the water drops or snowflakes don't generate non-desired actions to avoid the risk of errors or bugs.

> ⚠️ **In case of rain or snow, we encourage you to protect as much as possible the operating touch screen and regularly wipe the water drops or the snowflakes on the touch screen.**

8.4 Reset procedure

If the device is still locked/blocked, the **Reset** function can be activated using the instructions hereafter:
- Use a fine tip tool (paper clip or sharp pencil),
- Turn the monitor around and open the back compartment,
- Move the sensors away to find the **connectors' compartment**,
- Press the tip of your tool in the opening of the **Reset** button located at **the top left** corner of the compartment,
- Press and hold for a few seconds then release: the system reboots automatically.

23. Location of the connectors
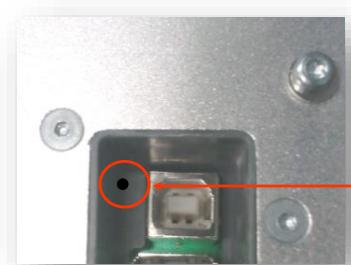
24. Location of the Reset button

8.5 Metrological check

The metrological check of the device has been fixed to **1 year maximum**, and must be done by the technical services of PARSYS Telemedicine. That service alone is the only one able to guarantee the operational metrological performances of the device during its entire running life.

8.6 Product Scrap Treatment

According to the directive 2002/96/CE relating to DEEE electronic and electric devices, do not throw away in regular trash. Please bring waste to specialized collection points.

8.7 Checking the pressure static accuracy of the blood pressure arm cuff / Air leakage measurement of the blood pressure arm cuff.

To check the static accuracy and the arm cuff air leakage pressure, you should first made a test bench by following one of two possible schemes:
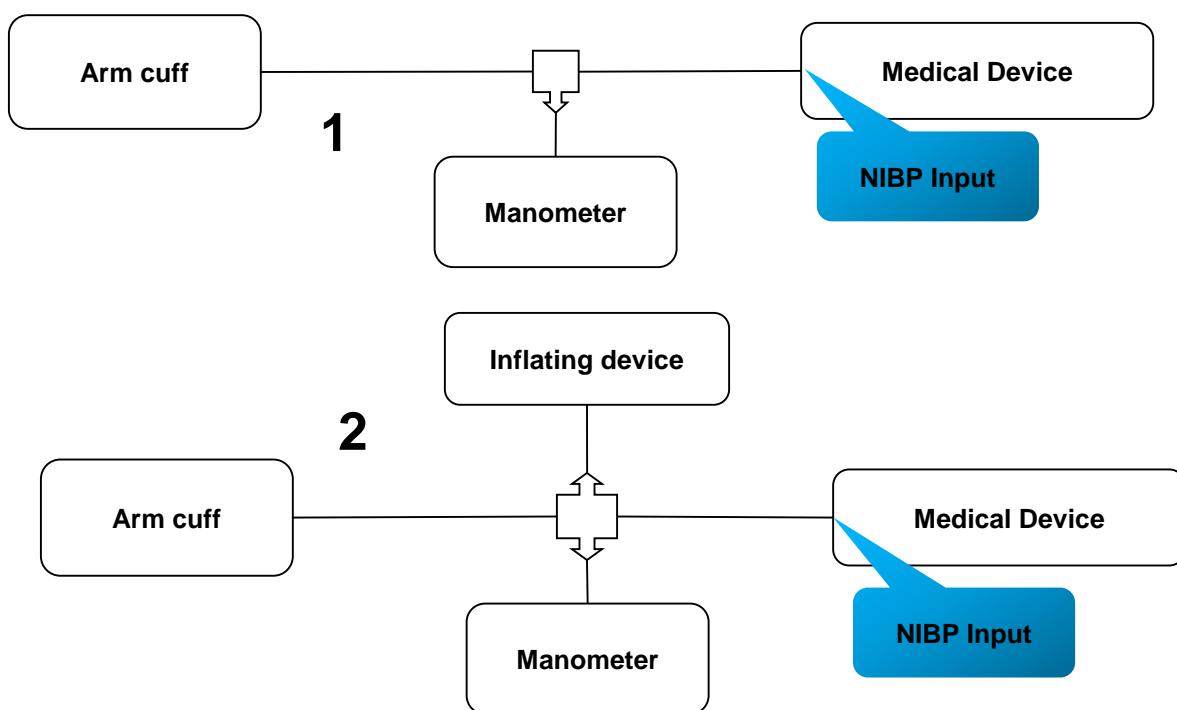
When the test bench is made, please follow the following procedure:

1. From the main screen, press the "**Settings**" button .

2. Press on the "**Calibration**" button .

3. A dialog allows the operator to select the initial arm cuff pressure, depending on the operation mode, either Adult, Neonatal or even manual.
   This value can be adjusted within the following ranges:
   - Adult: 140-180 mmHg
   - Neonat: 70-100 mmHg
   - Manual: 10-200 mmHg
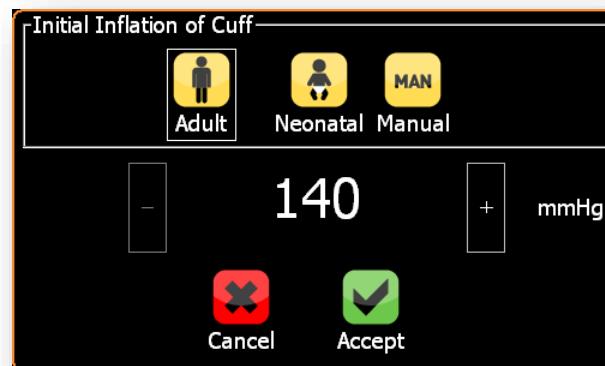
25. Arm cuff initial pressure settings window

4. During the test, a dialog displays in continuous the arm cuff pressure measure.

26. Arm cuff pressure measure test dialog

9. <u>Trained users</u>

It is **imperative** that users of Parametrys:
- have medical knowledge of doctor or nurse,
- hold the associate degree,
- have been trained in use of the device.

10.   Troubleshooting

10.1   Forced shut down of the system – Reset function

When the system is locked/blocked, the forced shut down of the Parametrys monitor can be obtained by **pressing continuously on the ON/OFF button** on the front side of the monitor, until the green light of the ON/OFF button disappears.

If the device remains blocked, the Reset function can be activated (see procedure described in 8.4.).

10.2   No main screen when the device lights on

When turning on the monitor, the software main screen (see 4.1) should appear after about one minute.

⚠️   **If the main screen is not compliant to the screen showed in 4.1 (following the options):**
- ▪   **You NEVER ATTEMPT to modify the software on your own.**
- ▪   **You contact the After-Sales Services of PARSYS Telemedicine for any questions.**

10.3   Software malfunctioning

The Parametrys monitor is delivered with a pre-installed, operational software. The possible software updates are done during maintenance. For each update, PARSYS Telemedicine will contact you and explain to you the updating procedure.

⚠️   **We please ask that:**
- ▪   **You NEVER ATTEMPT to install an update on your own.**
- ▪   **You contact the After-Sales Services of PARSYS Telemedicine for any questions.**

10.4   Wired sensors malfunctioning

We please ask you to check that:
- ▪   The sensors are correctly plugged in,
- ▪   The capturing protocol is respected (see 4.4),
- ▪   The sensors do not show any sign of damage.

10.5   Charging light of the monitor is Orange or Red, without any sound signal

When the charging light of the monitor is Orange or Red, there is a critical low level of battery.

In that case, you must:
- ▪   Turn off the device immediately:
  - o   By pressing the ON/OFF button in front of the monitor **for at least 3 seconds**, until the light of the button disappears,
  - o   Or by applying the reset procedure described in 8.4,
- ▪   Plug the monitor on a power source with the provided cord,
- ▪   Wait for the full recharge,
- ▪   Restart the monitor.

10.6   Charging light of the monitor is Red, with piercing sound signal

When the charging light of the monitor is **RED accompanied by a piercing sound single**, Windows signals a **major** error.

In that case, you must immediately turn off the device:
- By pressing the ON/OFF button in front of the monitor **for at least 3 seconds**, until the light of the button disappears,
- Or by applying the reset procedure described in 8.4.

You can then restart the monitor.

> ⚠️ **If you cannot restart the monitor, it must absolutely be sent back to the After-Sales Services of PARSYS Telemedicine.**

11. PARSYS Telemedicine Warranty and After-Sales Service

The Customer agrees to comply with the Warranty Conditions listed on the Warranty Certificate accompanying the Equipment.

The Equipment is supplied with a one-year (1) warranty during which period the Customer will be able to exchange Equipment found to have a latent defect and subject to the Customer having informed PARSYS Telemedicine thereof in writing and in detail.

In the event of a functional fault or failure of the Equipment, the Customer may contact PARSYS Telemedicine:
- by sending an e-mail to **support@parsys.com**,
- or by calling the PARSYS Telemedicine After-Sales Service:
  - Monday to Friday, 10 a.m. to 12.30 p.m. and 2 p.m. to 6 p.m., except for holidays,
  - at **+33 (0)1 60 31 51 71**
- or by sending a letter by recorded delivery with acknowledgement of receipt to:

PARSYS Télémédecine - After-Sales Service
5-7, avenue de Paris 94300 Vincennes - FRANCE

The PARSYS Telemedicine After-Sales Service identify the nature of the fault or failure of the Equipment before carrying out any repairs or replacing the defective Equipment.

Beyond the warranty period, the Customer has the possibility of subscribing to a maintenance contract with the PARSYS Telemedicine sales service.